

REMARKS

In view of the preceding amendments and the comments which follow, and pursuant to 37 CFR §1.111, amendment and reconsideration of the Official Action of June 17, 2005 is respectfully requested by Applicant.

Claims 16-18, 25, 28-31, 34-42, and 45 have been cancelled. Claims 1, 2, 6, 12, 13, 19, 20, 23, 26, and 27 have been amended. New claims 51-54 have been added. Support for the recitation "straight or branched chain" added to claims 1 and 19 is found on page 9, line 18 of the originally filed application. The subject matter of new independent claims 51 and 53 was previously included in claim 1 as filed. Previously, claim 1 was drawn to a hapten, an immunogen, and a label. Now these compounds have been separated into individual claims to simplify prosecution. New claim 52 depends from new claim 51 and tracks dependent claim 7. New claim 54 tracks claim 48 with the exception that it depends from claim 27. No new matter has been added.

Claims 1-15, 19-24, 26-27, 32-33, 48, and 51-54 remain pending for examination.

Double patenting rejections

Claims 17, 18, and 31 have been provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of copending application serial no. 11/076,569, a divisional of serial no. 10/087,612.

Claims 17, 18, 31 and 42 have been again provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 16, 26, and 33 of copending application no. 10/622,254.

Applicant has now cancelled claims 17, 18, 31, and 42, thereby rendering these double patenting rejections moot. Reconsideration is respectfully requested.

Rejection under 35 USC §102 (e)

Claims 1-42, 45 and 48 have been rejected under 35 USC §102 (e) as being anticipated by Rouhani et al., U.S. 2003/0207469 (hereinafter "Rouhani"). The examiner argues that

Rouhani describes methylenedioxy(meth)amphetamine derivatives wherein a linker-functional group, linker-immunogenic carrier, or linker-label (defined by " L_n^1-Z ") is attached to the nitrogen atom of the phenethylamine moiety. The linker is inclusive of the definitions of the linker moiety " $J-M$ -" of the instant claims. See page 4, paragraph [0040], page 3, paragraphs [0028]-[0034]. The compounds of Rouhani anticipate the (meth)amphetamine haptens, immunogens, and tracers of instant claim 1. The antibody and method of producing the antibody from the immunogen (instant claims 17 and 34) are described in paragraphs [0044] and [0045] of the reference. The conventional use of the antibody in an immunoassay (instant claim 42) is described in paragraph [0051] of the reference.

Applicant traverses the rejection. Applicant's claims as now amended as well as new claims 51-54 are drawn to protected compounds, i.e., compounds wherein R^2 is a protecting group. Claim 1 is drawn to the protected hapten of Applicant's invention, while claims 51 and 53 are drawn to the protected immunogen and the protected label, respectively, of Applicant's invention. Briefly, the synthetic process of the instant invention involves, in the case of an immunogen, going from protected activated hapten to protected immunogen to deprotected immunogen. The protecting group for the hapten amine is key to Applicant's invention. In synthesizing immunogenic derivatives according to the invention, amine groups on a macromolecular carrier are targeted, and in order to do so, the amine group on the hapten must be protected. Rouhani, on the other hand, targets thiols, not amines. Rouhani teaches and enables only maleimide derivatives and does not teach or suggest protecting the hapten amine. For the examiner's information, schematic drawings showing precisely what Rouhani teaches in each example has been attached hereto. Protection of the hapten amine is the key distinguishing factor between the instant invention and the teaching of Rouhani. With the present amendments which recite that the hapten amine be protected (" R^2 is a protecting group") and in which maleimidothioether is no longer included in the Markush expression defining M, Applicant asserts that this rejection is now overcome. The examiner's reconsideration of the rejection as applied to currently pending claims 1-15, 19-24, 26-27, 32-33, 48, and 51-64 is respectfully requested.

Rejection under 35 USC §102 (b)

Claims 17 and 18 have been rejected under 35 USC §102 (b) as being anticipated by Brynes et al., U.S. Patent No. 5,101,015 (hereinafter "Brynes"). The Examiner notes that Applicant failed to specifically address this rejection in his reply to the previous office action. Applicant respectfully apologizes for this oversight.

By way of the present amendment, claims 17 and 18 have been cancelled, thereby rendering the rejection moot. The examiner's reconsideration is requested.

Applicant submits that his application is now in condition for allowance, and favorable reconsideration of his application in light of the present amendments and above remarks is respectfully requested. Allowance of claims 1-15, 19-24, 26-27, 32-33, 48, and 51-54 at an early date is earnestly solicited.

The examiner is hereby authorized to charge any fees associated with this amendment to Deposit Account No. 02-2958. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

A handwritten signature in cursive script, reading "Marilyn Amick". The signature is written in dark ink and is positioned above the printed name and registration number.

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